Attachment 1

MSD Phone Screening Procedures

OMB Control Number: 0925-XXXX Expiration Date: XX/XX/XXXX

Public reporting burden for this collection of information is estimated to average 10 minutes per response,

including the time for reviewing instructions, searching existing data sources, gathering and maintaining

the data needed, and completing and reviewing the collection of information. An agency may not conduct

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currently valid OMB control number. Send comments regarding this burden estimate or any other aspect

of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance

Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do

not return the completed form to this address.

MSD Phone Screening Procedures

Overview:

The purpose of this research study is to characterize the effects of <insert drug name> on driving performance.

Study Information, Time Commitment and Compensation:

Participating in this study involves 3 visits. One of which is a 45 minute screening visit and two 5-6 hour dosing visits.

Screening Visit:

For this visit you will be required to come to the University Research Park located on Oakdale Blvd in Coralville to participate. At this visit:

- First we will obtain your written consent
- Review the inclusion/exclusion criteria
- Review simulator and complete simulator drive
- Ask you to provide a urine sample for a urine drug screen
- Females: our urine sample will be screened for pregnancy
- Have you complete a survey about your driving experiences and demographic information

Dosing Visits:

These visits are spaced about one week apart and begin at 8 am. We will arrange third party transportation to bring you to our research facility.

Are you still interested in participating?

▶ If YES, continue with Inclusion Criteria

Inclusion Criteria ~ General Questions

Overview

Before this list of questions is administered, please communicate the following:

• There are several criteria that must be met for participation in this study. I will need to ask you several questions to determine your eligibility.

Proceed to Closing if an answer does not meet study criteria.

- 1) Do you possess a valid U.S. Drivers' License?
- 2) How long have you been a licensed driver?
- 3) What restrictions do you have on your license?
- 4) How many miles do you drive per year?
- 5) Do you require any special equipment to help you drive such as pedal extensions, hand brake or throttle, spinner wheel knobs or other non-standard equipment?
- 6) How old are you?
- 7) How far do you live from University of Iowa Research Park which is North of the Coral Ridge Mall?
- 8) Are you able to attend three study visits with one being approximately 45 minutes and two visits of approximately 5-6 hours?

General Questions Inclusion Criteria is met – proceed to Specific Cannabis Inclusion Questions or General Health Exclusion Criteria

Specific Cannabis Inclusion Questions

Proceed to Closing if an answer does not meet study criteria.

1) How frequently do you use cannabis?

Specific Inclusion Criteria is met – proceed to General Health Exclusion Criteria

General Health Exclusion Criteria

1.1.1 Overview

- 1.1.2 Before administering this list of questions, please communicate the following:
- 2 Because of pre-existing health conditions, some people are not eligible for participation in this study.
- 3 I need to ask you several health-related questions before you can be scheduled for a study session.
- 4 Your responses are voluntary and all answers are confidential.
- 5 You can refuse to answer any questions
- 6 No responses will be recorded.
 - If a participant fails to meet one of the following criteria, proceed to the Closing

1) If the subject is female:

- Are you, or is there any possibility that you are pregnant? Or, are you currently breast feeding?
- 1) 2 Do you have or have you been diagnosed with a sleep disorder, or do you have a family history of sleep disorders?
- 2) Do you have a neurological or pulmonary disorder or are you taking medications to treat such a disorder?
- **3)** Have you been diagnosed with a psychiatric disorder or are you taking medications to treat such a disorder?
- 4) Do you have an eating disorder?
- 5) Do you regularly use prescription pain medication?
- 6) Have you had a head injury within the past five years, or are you still experiencing symptoms from a prior head injury?
- 7) Do you have a history of high blood pressure, heart disease, diabetes or stroke, or are taking medications to treat these conditions?
- 8) Do you have a behavioral or attention disorder or take medications to treat these conditions?
- 9) Do you have untreated or untreatable vision or auditory conditions?
- 10) Do you have seasonal allergies, or take medication to treat any type of allergies?
- 11) Do you smoke cigarettes more than 10 times per day?
- 12) Do you have twenty or more alcoholic beverages per week?
- 13) Do you consume five or more servings of caffeinated beverages per day?
- 14) Do you use illicit drugs or taken prescription medications that are not prescribed for you?